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4. Program Regulations

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427.401: Introduction

130 CMR 427.000 establishes the requirements and procedures for the purchase, rental, and repair of oxygen and respiratory therapy equipment and supplies under the Medical Assistance Program.

427.402: Definitions

The following terms used in 130 CMR 427.000 ~~shall~~ have the meanings given in 130 CMR 427.402 unless the context clearly requires a different meaning.

Accessory Equipment — a product fabricated primarily and customarily to modify or enhance the usefulness or functional capability of other equipment and that is generally useful only in the presence of other equipment.

Apnea Monitor — a device that has the ability to recognize central or mixed apneas and bradycardia as they occur and to record these events for subsequent review. It must:

- (1) have alarms that accurately reflect the predisposing condition and that consistently alert and are understandable to the caregiver;
- (2) be capable of monitoring its own internal essential functions to assure proper operation;
- (3) be noninvasive; and
- (4) be easy to use and understand.

Adjusted Acquisition Cost — the price paid to a supplier by a provider for oxygen and respiratory therapy equipment, excluding all associated costs such as, but not limited to, shipping, handling, and insurance costs.

Customized Equipment — durable medical equipment that is made or adapted to meet the specific needs of a particular patient and that is sufficiently specialized or modified to preclude the use of such equipment by subsequent patients. Customized equipment may be either custom fabricated or custom fitted.

- (1) custom fabricated — equipment made for a patient from measurement or patterns, or both.

The following list describes various types of custom-fabricated equipment:

- (a) casting — encasing a body part in a cast;
 - (b) molded to patient model — equipment that is fabricated from a positive mold developed from a plaster cast taken of the involved portion of the patient's body;
 - (c) non-molded — no casting or molding techniques are used in the fabrication of the equipment, which may be either a stock item or made from measurement or patterns, or both.
- (2) custom fitted — no casting or molding techniques used in the fabrication of the equipment, which is a stock item that is fitted and adjusted to the patient.

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Durable Medical Equipment — products that are:

- (1) fabricated primarily and customarily to fulfill a medical purpose;
- (2) generally useful only in the presence of illness or injury;
- (3) able to withstand repeated use over an extended period of time; and
- (4) appropriate for home use.

EOHHS – the Executive Office of Health and Human Services established under M.G.L. c. 6A.

Licensed Physician — a physician who is licensed by the Massachusetts Board of Registration in Medicine or by the appropriate board of registration in the state in which the physician practices.

Licensed Respiratory Care Practitioner — a respiratory therapist or technician recognized by the Commonwealth of Massachusetts, Division of Registration, as qualified to provide respiratory care services in Massachusetts.

MassHealth – the medical assistance and benefit programs administered by EOHHS pursuant to Title XIX of the Social Security Act (42 U.S.C. 1396), Title XXI of the Social Security Act (42 U.S.C. 1397), M.G.L. c.118E, and other applicable laws and waivers to provider and pay for medical services to eligible members.

Medical and Surgical Supplies — medical products that are:

- (1) fabricated primarily and customarily to fulfill a medical or surgical purpose;
- (2) generally useful only in the presence of illness or injury;
- (3) used in the treatment of a specific medical condition; and
- (4) nonreusable and disposable.

Member (formerly “recipient”) — a person determined by the MassHealth agency to be eligible for MassHealth.

Oximetry — provides estimates of arterial oxyhemoglobin saturation (SaO₂) by utilizing selective wavelengths of light to determine noninvasively the percentage of hemoglobin saturated with oxygen.

Oxygen — gaseous or liquid medical-grade oxygen that conforms to United States Pharmacopoeia Standards.

Oxygen and Respiratory Therapy Equipment — equipment and supplies used in the administration of oxygen therapy or the administration of respiratory therapy.

Oxygen and Respiratory Therapy Equipment Provider — an organization or individual that has enrolled with MassHealth and has signed a provider contract with the MassHealth agency that meets all applicable requirements of 130 CMR 427.404 and 130 CMR 450.000: Administrative and Billing Regulations. Oxygen and respiratory therapy equipment providers may include MassHealth providers also enrolled as MassHealth participating durable medical equipment and supplies (DME) providers, orthotic services providers, or prosthetic services providers who meet all program-specific requirements; and pharmacy providers eligible to enroll with an oxygen specialty under 130 CMR 427.404(B), who also meet all applicable requirements of 130 CMR 427.000.

Oxygen-Generating Equipment — any device suitable for domiciliary use that produces oxygen by

any chemical or physical means, such as, but not limited to, oxygen concentrators and oxygen enrichers, and that conforms to such standards as may be required by federal or state law.

Oxygen Delivery Systems — a comprehensive oxygen service that includes, but is not limited to, gaseous and liquid oxygen, oxygen-generating equipment and related delivery-systems container or cylinder, manifold system whenever high-volume oxygen is used, stand, cart, walker or stroller, supply reservoir, contents indicator, regulator with flow gauge, humidification devices, cannula, mask, and special administration device tubing and refill adapter.

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Oxygen Therapy — the administration of oxygen at concentrations greater than that in the ambient air with the intent of treating the signs and symptoms of tissue hypoxia resulting from abnormal blood oxygen levels.

Respiratory Therapy — treatment that maintains or improves the ventilatory function of the respiratory tract.

Respiratory Therapy Equipment and Supplies — modalities and necessary ancillary equipment generally used in the care and treatment of pulmonary insufficiency that are prescribed by a licensed physician or independent nurse practitioner for therapeutic and remedial effect and that meet standards required by federal or state law. Respiratory therapy devices include, but are not limited to, the complete device and its related delivery-system accessories, including regulator, humidification and heating units, filters, cannulas, masks, and special administration device tubing adapters.

Servicing Facility — a business or branch of a business where oxygen and respiratory therapy equipment, supplies, and services, especially repairs and replacements, can be obtained.

Usual and Customary Charge — the lowest fee charged by an oxygen and respiratory therapy equipment provider to the general public.

427.403: Eligible ~~Recipients~~Members

(A) MassHealth Members. MassHealth covers oxygen and respiratory therapy equipment provided to eligible MassHealth members, subject to the restrictions and limitations described in regulations at 130 CMR 427.000 and 450.000: *Administrative and Billing Regulations*. 130 CMR 450.105: *Coverage Types* specifically states, for each coverage type, which services are covered and which members are eligible to receive those services.

(B) Recipients of the Emergency Aid to the Elderly, Disabled and Children Program. For information on covered services for recipients of the Emergency Aid to the Elderly, Disabled and Children Program, see 130 CMR 450.106: *Emergency Aid to the Elderly, Disabled and Children Program*.

(C) Verification of Member Eligibility. For information about verifying member eligibility and coverage type, see 130 CMR 450.107: *Eligible Members and the MassHealth Card*.

~~(A) Medical Assistance RecipientsMassHealth Members. The services described in 130 CMR 427.000 are reimbursable for all Medical Assistance recipientsMassHealth members (categories of assistance 0, 1, 2, 3, 5, 6, 7, and 8), subject to the restrictions and limitations in 130 CMR 427.000.~~

~~(B) Recipients of the Emergency Aid to the Elderly, Disabled and Children Program. For information on reimbursable services for recipients of the Emergency Aid to the Elderly, Disabled and Children Program (category of assistance 4), see 130 CMR 450.111.~~

427.404: Provider Eligibility

(A) Participating Provider Requirements. Payment for the services described in 130 CMR 427.000 are is made only to providers of oxygen and respiratory therapy equipment providers and repair service providers who are participating in the Medical Assistance ProgramMassHealth; to providers also enrolled as MassHealth participating durable medical equipment and supplies

(DME) providers, orthotic services providers, or prosthetic services providers who meet all program-specific requirements; and to MassHealth-enrolled pharmacy providers who have been assigned an oxygen and respiratory therapy equipment specialty in accordance with 130 CMR 427.404(B). Participating oxygen and respiratory therapy equipment providers must be accredited by an accrediting body that is acceptable to the Centers for Medicare & Medicaid Services. Applicants must meet the requirements in 130 CMR 450.000: *Administrative and Billing Regulations*, as well as the requirements in 130 CMR 427.000. Participating oxygen and respiratory therapy equipment providers must continue to meet provider eligibility participation requirements throughout the period of their provider contract with the MassHealth agency, as of the date of service and who are accredited by the Joint Commission on Accreditation of Health-Care Organizations (JCAHCO) as oxygen and medical equipment providers.

(B) Pharmacy Providers Assigned Oxygen and Respiratory Therapy Equipment Specialty. Applicants or providers enrolled as a MassHealth pharmacy provider under 130 CMR 406.000: *Pharmacy Services* may qualify to provide oxygen and respiratory therapy equipment services if the following conditions are met:

- (1) the applicant or provider meets all other conditions under CMR 427.000 to provide oxygen and respiratory therapy equipment and supplies; and
- (2) the MassHealth agency has assigned a specialty of oxygen and respiratory therapy equipment to the applicant's or provider's existing provider number for pharmacy services.

(CB) In State.

- (1) A provider located in Massachusetts must ~~primarily~~ engage in the business of supplying oxygen and respiratory therapy equipment to the public and must meet all state and local requirements for engaging in such business.

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(2) A provider located in Massachusetts must employ a minimum of one respiratory care practitioner licensed by the Commonwealth of Massachusetts.

(3) A provider who furnishes services to recipients in Massachusetts and whose main office is located out of state must have a servicing facility in Massachusetts.

~~(DE)~~ Out of State. A provider located outside of Massachusetts is eligible to participate in ~~the Massachusetts Medical Assistance~~MassHealth Program only if it participates in the ~~medical-assistance~~Medicaid program (or equivalent) of the state in which it primarily conducts business and meets the requirements in 130 CMR 427.404(A).

427.405: Services Provided by Out-of-State Providers

The Division pays for services provided in another state to the same extent that it pays for services within its boundaries if the services are provided to a recipient who is a resident of Massachusetts and any of the following conditions are met:

- (A) services are needed because of a medical emergency;
- (B) services are needed and the recipient's health would be endangered if the recipient were required to travel to the Commonwealth;
- (C) the Division determines, on the basis of medical advice, that the needed services, or necessary supplementary resources, are more readily available in another state; or
- (D) the recipient lives in an area of Massachusetts that borders another state, and it is a general practice of recipients in that area to use medical resources in the adjacent state.

427.406: Reimbursable Services

The Division pays for the purchase, rental, and repair of oxygen and respiratory therapy equipment and supplies subject to the restrictions and limitations in 130 CMR 427.000.

427.407: Nonreimbursable Services

The Division does not pay for the following equipment and services:

- (A) any equipment or services that are investigative or experimental in nature;